

***USDA Process Verified Program - Seed
USA Accredited Seed Sampling Program (ASSP)
Specified Program Requirements***

1 Purpose

The purpose of this document is to set forth the policies, procedures and requirements of the USA Accredited Seed Sampling Program (ASSP) and for the independent process verification of participants in the ASSP. The ASSP is a voluntary, user-fee service available to seed sampling entities or individuals. Seed samplers, which meet all requirements of this program and successfully pass a USDA Process Verified Program Audit, will be able to represent themselves as a USA Accredited Seed Sampler.

2 Scope

- 2.1 The ASSP applies to seed samplers or sampling entities seeking accreditation under this program. The USDA Agricultural Marketing Service (AMS) will conduct independent process verification audits of the seed sampler's documentation and procedures with regard to the ASSP.
- 2.2 This document describes the requirements for accreditation for seed sampling only.

3 Objective

The objective of the USA ASSP is to provide uniform procedures and methodology for sampling seed lots. The ASSP will enhance seed movement both domestically and globally through standardized, verified processes. Adherence to the program requirements and quality standards of the USDA Process Verified Program will further enhance the quality and consistency of seed sampling in the US.

4 Additions to the USDA Process Verified Program (PVP) Requirements

The specific program requirements listed in Section 7 of this Procedure must be met through an approved USDA Process Verified Program (PVP). The USDA PVP ensures that the specified program requirements are supported by a documented quality management system. In addition to the requirements listed in the ARC 1001 Procedure, companies/entities must also incorporate the following reference documents, definitions, and program requirements into their USDA Process Verified Program:

5 Reference Documents

- 5.1 ***ARC Procedure 1000 Quality Systems Verification Program General Policies and Procedures.***
- 5.2 ***ARC Procedure 1001 Process Verified Program***

- 5.3 **International Organization for Standards (ISO) Guide 65, *General requirements for bodies operating product certification systems.***
- 5.4 **AASCO Seed Sampling Handbook**, as amended
- 5.5 **OECD Seed Schemes**
- 5.6 Documents referenced above may be obtained from the USDA web site:
www.ams.usda.gov/lsg/seed.htm

6 Definitions

- 6.1 Accredited Seed Sampler: Any seed sampler or sampling entity meeting all requirements of the ASSP. USDA deems samplers accredited who work under an approved documented program that addresses the requirements of ASSP and upon successful completion of an audit by USDA or by USDA, AMS Recognized Auditors.
- 6.2 Accreditation Auditor Authority: USDA-AMS will have the authority to approve, deny or suspend a sampler's accreditation in accordance with the USA ASSP guidelines.
- 6.3 Product: For the purpose of the ASSP, the term "product" means the completed sample.
- 6.4 Program Documentation: Documents and records prepared and maintained by the accredited seed sampler that describe and record the sampling procedures that conform to the ASSP requirements. This documentation must be in the form of a well-defined quality manual, including controlled program documents and records that meet all ASSP requirements.
- 6.5 Program Guidelines: The original program was developed and incorporated by a task force composed of AASCO and USDA representatives.
- 6.6 Recognized Auditors: Audit, Review and Compliance Branch Quality Systems Auditors and audit programs that are approved by AMS using International Organization for Standardization (ISO) Guide 65, General requirements for bodies operating product certification systems. Audit systems must include both a technical and systems auditing component in accordance to ISO Guide 65 requirements.
- 6.7 Surveillance Audit: A review of the accredited seed sampler's facilities, procedures and records (1) to determine conformance with this Program, and (2) to verify the participants ability to meet all of the requirements of the USA ASSP. These audits will be conducted by the AMS Livestock and Seed Program, Audit, Review and Compliance (ARC) Branch or by AMS recognized auditors.

7 Specified Program Requirements

- 7.1 Participation in this program is voluntary.
- 7.2 Accredited seed samplers must maintain an approved Quality Management System and Standard Operation Procedures that meet all the applicable elements as outlined in ***ARC Procedure 1001 Process Verified Program***. All program documentation must be available for review by the USDA Auditor or its designee.
- 7.3 Conformance with the ASSP requirements will be determined through fee-for-service, process verified, surveillance audits conducted by AMS, or its designee using the USA ASSP, ***ARC Procedure 1000 Quality Systems Verification Program General Policies and Procedures and ARC Procedure 1001 Process Verified Program***.
- 7.4 Accredited seed samplers will be accountable to sample seed in accordance with AASCO Seed Sampling Handbook, OECD Authorization Guidelines or the Federal Seed Act.

8 Samplers or Sampling Entities Responsibilities

- 8.1 Accredited seed samplers must conduct an internal audit annually and supply the results of the internal audit to AMS prior to its anniversary date listed on the USDA web site. Internal audits must review all activities within the scope of the accreditation and can be performed by the accredited seed sampler or by an outside agency.
- 8.2 Accredited seed samplers will be audited to determine expertise and implementation during actual sampling activities.
- 8.3 A portion of the seed lots entered for official certification for OECD shall be check-sampled by official seed samplers. That portion shall be at least 5 per cent. Check sampling shall not apply to seed lots that have been sampled by approved automatic samplers.
- 8.4 Comply with all provisions of this program and applicable elements of ***ARC Procedures 1001, Process Verified Program***.
- 8.5 Maintain complete records demonstrating conformance with the ASSP. Records shall be maintained for a minimum of five (5) years. Records can be disposed of at the beginning of the sixth year after the year in which they were created.
- 8.6 Immediately notify AMS of any significant changes in the approved program documentation used to verify conformance to the ASSP.

- 8.7 Notify AMS to cancel service prior to the next surveillance audit when service is no longer desired.

9 AMS Responsibilities

- 9.1 Conduct audits according to this Procedure, *ARC Instruction 1000 Quality Systems Verification Program General Policies and Procedures*, and *ARC Instructions 1001 Process Verified Program*.
- 9.2 Maintain and publish a listing for the ASSP at www.ams.usda.gov/lsg/seed.htm
- 9.3 Records should be maintained for five (5) calendar years after the year in which the external audit was conducted.

10 Surveillance Audits

- 10.1 *ARC 1000 Procedure Quality Systems Verification Programs General Policies and Procedures* and the requirements outlined in this program will be used to assess seed samplers and seed sampling entities.
- 10.2 All accredited seed samplers will be audited at least every three (3) years. More frequent audits may be conducted if either numerous minor non-conformances or a major non-conformance are identified during an audit.
- 10.3 AMS reserves the right to conduct a case specific surveillance audit at any time at the cost of the participant. A surveillance audit could be triggered by a written complaint, which has been investigated and deemed valid by USDA, or a non-conformance issue relating to the audit process.
- 10.4 Program audits will be conducted by AMS or its designee and will include both a technical and system auditing component.

11 Approval Procedures

ARC 1000 Procedure Quality Systems Verification Programs General Policies and Procedures, *ARC Procedure 1001 Process Verified Program*, and the requirements outlined in this procedure will be used to approve or deny seed samplers or seed sampling entities.

12 ARC Branch Contact Information

All program documentation, updates, internal reviews and proficiency testing results should be submitted to the following address:

USDA, AMS, LS, ARC Branch
Stop 0294, Room 2627-S

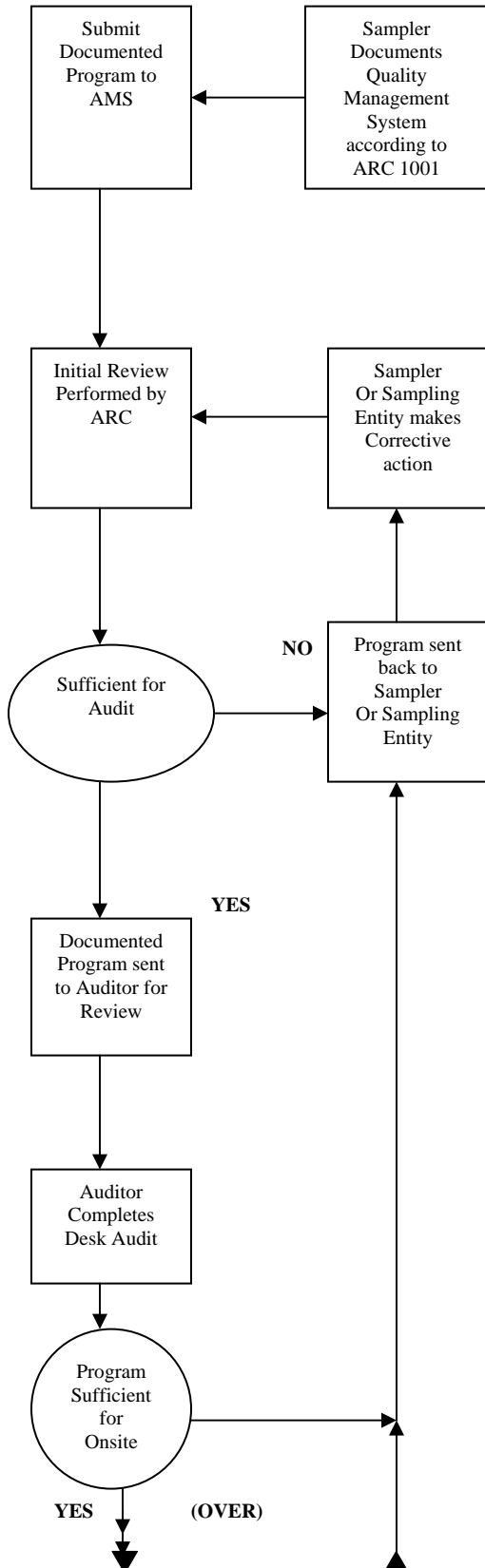
100 Riverside Parkway, Suite 135
Fredericksburg, VA 22406
Phone: (540) 361-7640
Fax: (540) 361-7859 or (202) 690-1038

13 Publication

Information about each accredited seed sampler program will be posted on the USDA-AMS Internet website at: www.ams.usda.gov/lsg/seed.htm. Information posted will include the name, address and scope of accreditation.

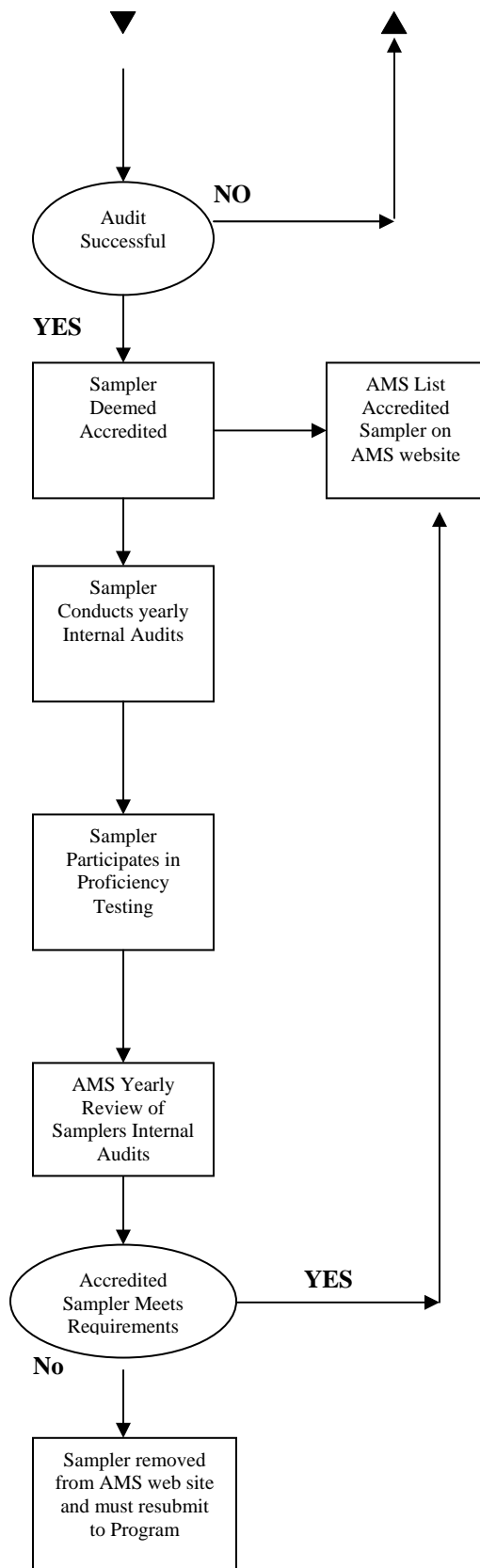
14 Confidentially

All materials submitted by applicants and maintained by AMS are subject to disclosure under the Freedom of Information Act. The Freedom of Information Act applies to documents that are in the control of or maintained by a government agency. AMS does not maintain program manuals submitted by applicants. These manuals are reviewed by a branch auditor and returned to the applicant upon completion of the audit process. AMS will make appropriate provisions to protect proprietary information from disclosure to the extent possible under existing Federal laws. Any portion of the program documentation that the applicant considers proprietary must be identified at the time the information is submitted along with written justification why said documents should not be released to or reviewed by the public. Any information deemed a trade secret or confidential business information cannot be released to the public.



USA ACCREDITED SEED SAMPLING PROGRAM (ASSP)

1. The applicant documents its Quality Management System (QMS) according to *ARC 1001, Process Verified Program* and current USA ASSP procedure.
2. The sampling entity requests an initial assessment by submitting the following to the ARC Branch.
 - A completed and signed *Application for Service, LS Form 313*.
 - A cover letter requesting an ASSP audit.
 - The Quality management program documentation used to ensure conformance to the applicable elements of *ARC Instruction 1001, Process Verified program* and the ASSP requirements.
3. The ARC Branch performs the initial review. If the submitted program is sufficient, it is then sent to an auditor.
4. AMS will assign a qualified ARC Branch auditor, or an approved recognized audit program chosen to perform an audit as soon as possible upon determining that the *Application – LS Form 313* and QMS program documentation is sufficient.
5. An auditor will complete a desk audit of the program, interacting with the sampler as necessary.
6. The auditor will schedule the onsite visit once the program is determined to be sufficient.
7. All audits will be conducted according to *ARC Instruction 1000 Quality Systems Verification Program General Policies and Procedures, and ARC Instructions 1001 Process Verified Program*.



9. AMS will prepare a detailed report of the audit observations, findings and a recommendation. AMS will then forward the audit report and the final decision to the accredited sampler or sampling entity. AMS will ensure surveillance audits are performed as required by this procedure and provides overall program review and approvals.

10. The sampler or sampling entity must address any non-conformances found during the audit within a reasonable time frame.

11. Approval. A sampler or sampling entity that conforms to the ASSP procedure and their approved QMS program documentation will be considered accredited. Once accredited, the ARC Branch will post the seed sampler *programs information*.

12. Accredited seed samplers or seed sampling entities must conduct an internal audit yearly and supply a copy of the results to AMS prior to their anniversary date on the USDA official web listing. Internal audits must review all activities within the scope of the accreditation and can be self-performed or contracted with an outside agency.

13. Accredited seed samplers or seed sampling entities must participate in recognized proficiency testing.

14. Accredited seed samplers or sampling entities will be audited every three (3) years. However, more frequent audits may be conducted if either numerous continuous improvement points or hold points are identified during any audit.

15. AMS reserves the right to conduct a case specific surveillance audit during the three (3) year period, at the cost of the participant. A surveillance audit could be triggered by a written complaint, which has been investigated and deemed valid by USDA, or a non-conformance issue relating to the approval process.